TAB 2
Introduction

## INTRODUCTION

This document provides information in support of the rule-making for Topical Antimicrobial Drug Products for Over-the-Counter Human Use; Tentative Final Monograph for Health-Care Antiseptic Drug Products (TFM) 59 Fed. Reg. 31401 (June 17, 1994).

The Soap and Detergent Association and The Cosmetic, Toiletry, and Fragrance Association Industry Coalition (Coalition) has made a number of submissions to FDA providing data and comments pertinent to this rule-making[1]. The Coalition continues to advocate that the Agency should develop a Monograph that encompasses all of the categories of topical antimicrobial products of the Healthcare Continuum Model[2] (HCCM) as many unresolved issues in the TFM are fundamental to all products in the HCCM. In August 2001, recognizing that the Agency was developing the rule-making for products designated as "healthcare professional products", the Coalition submitted a Citizen Petition detailing proposed methods and performance criteria for pre-operative skin preparations, surgical scrubs, and healthcare personnel hand products. This Petition complements the August 2001 healthcare professional products submission by providing data on the remaining product categories that comprise the HCCM, namely food handler, consumer hand, and consumer body products.

The HCCM proposes that there is a continuum of risk from infection transmitted by microorganisms on the skin. The severity of the risk is dependent upon the specific task or setting and upon underlying conditions such as susceptibility of the host. While topical antimicrobial products should be formulated and labeled with indications to address specific situational risks, the actual level of risk to an individual may overlap one or more product categories, *i.e.,* there is a continuum of risk among the HCCM product categories. Splitting the healthcare professional products from the other HCCM categories is artificial and potentially misleading.

Healthcare is no longer limited to the health professions. It extends from the home through the surgical suite. The risks mitigated by the use of these healthcare professional products and the other categories overlap. Common issues of finished product test methodology and active ingredient status underpin all HCCM product categories. The Coalition requests that the Agency consider the entire HCCM, rather than addressing healthcare professional products separately from the other categories. If the Agency decides to split the topical antimicrobial monograph, we request that a statement be added in the Final Monograph for professional healthcare products that the remaining product categories of the HCCM will be addressed in future rule-making.

Products in this OTC Monograph largely provide a prophylactic benefit rather than a therapeutic benefit. The demonstration of a prophylactic benefit is more difficult than the demonstration of a therapeutic benefit. In the August 30, 2001 submission to the docket, the Coalition provided a summary of the benefit studies identified in the literature for both clinical and non-clinical settings. There are many more studies showing a benefit in hospital and other clinical settings, in part because the patients in those settings are very vulnerable and also because they are more easily

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[1] These have included: comments on the TFM and the proposal of the Healthcare Continuum Model (June 15, 1995), compilations of efficacy data (December 13, 1995 and March 11, 1996), a detailed proposal on finished product testing methodology (September 29, 1999), a Citizen Petition for proposed labeling of HCCM product categories (April 2, 2001), a Citizen Petition addressing several OTC monograph flexibility issues (June 1, 2001), a Citizen Petition on surrogate end-point test methods (November 28, 2001), a Citizen Petition providing information in support of healthcare professional products (August 30, 2001) and a Citizen Petition requesting anti-viral claims based on testing and evidence of efficacy (January 17, 2003).

[2] Proposed by the Coalition in its June 13, 1995 submission to the docket, the HCCM proposes a framework for the regulation of topical antimicrobial drug products consistent with public health needs in domestic, institutional and commercial settings. Within the HCCM framework, product efficacy qualification is based on the need to mitigate the risk of transmission of organisms or acquisition of disease in specific situations. Finished product testing, using standardized and qualified American Society for Testing and Materials (ASTM) methods, must demonstrate that a product meets threshold performance criteria for that product category.

studied due to the relatively controlled conditions that exist in those institutions. Studies conducted in industrial or domestic settings are much more difficult to control, and the level of susceptibility of the individuals to infection varies considerably. Existing studies that show the benefit of antimicrobial products in non-clinical situations usually involve large numbers of subjects (often in institutional settings) or represent very specific use situations. A number of such studies have been conducted and are detailed herein.

Additional support for the benefits of using topical antimicrobial products is provided by a number of studies using qualitative microbial risk assessment (QMRA), which are also included. QMRA can be used as a tool to provide systematic evaluation of the risk of potential infection associated with the acquisition or transmission of microorganisms in any setting. FDA has used QMRA to project the risk of a number of foodborne pathogens; EPA uses it extensively in the development of drinking and surface water regulations. The advantage of QMRA is that it permits an assessment of the consequences of an exposure in the absence of additional direct experiments on human subjects. It uses experimental data and literature data to develop appropriate discrete or probability distribution functions. A number of QMRA studies indicate that antimicrobial soaps can substantially reduce the risk of infection.

This Citizen Petition addresses three HCCM product categories, *i.e.,* food handler, consumer hand, and consumer body products and is complementary to the Citizen Petition for professional healthcare products submitted by the Coalition on August 30, 2001.

Section 1 reviews situations where food handler products, consumer hand products, and consumer body products are used and the range of expected exposure to microorganisms.

Section 2 briefly reviews the benefits of these products in domestic and institutional settings, proposes performance criteria and appropriate methods, and summarizes the data supporting these proposals.

Appendix A provides a tabular display of the efficacy data used to support the performance criteria.

Appendix B includes the Coalition's proposed labeling for the three categories discussed. This was previously submitted on April 2, 2001.

Finally, the Coalition is committed to working with the Agency to resolve all of the issues associated with this Monograph.